



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,796	11/17/2003	Kenneth W. Dobie	HTS-0016US.P1	2946

55389 7590 07/24/2006

KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

MCGARRY, SEAN

ART UNIT	PAPER NUMBER
----------	--------------

1635

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/714,796

Applicant(s)

DOBIE ET AL.

Examiner

Sean R. McGarry

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,13-19,23-28,44-60 and 68-72 is/are pending in the application.
- 4a) Of the above claim(s) 17-19,24-28,44-48 and 52-58 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 70-72 is/are allowed.
- 6) ☒ Claim(s) 1, 3-7, 13-16, 23, 49-51, 59, and 60 is/are rejected.
- 7) ☒ Claim(s) 68 and 69 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/20/04; 1/23/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election without traverse of Group IV in the reply filed on 5/16/06 is acknowledged.

Claims 17-19, 24-28, 44-48, and 52-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/16/06.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 50, 59 and 60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 50 was added in the preliminary amendment filed 1/23/04 and adds the limitation of an oligonucleotide "comprising two regions of LNA nucleotides flanking a region of 2'-deoxynucleotides". Applicant points to locations in the specification for support of the preliminary amendment in general and also point to the original claims and the specification in general for support for the preliminary amendment. The preliminary amendment does not point to any particular support for the specific limitation above. The locations specifically cited in the preliminary amendment do not provide support for the specific limitation above. Support for the above limitation is not readily apparent from the specification or claims as originally filed and the limitation is therefore considered new matter. If applicant believes that the specification and/or claims as originally filed provide support for the above limitation applicant should point to such support with particularity.

Claims 59 and 60 were added in the preliminary amendment filed 9/20/05. Claim 59 adds the limitation of an antisense compound "comprising two regions of 2'-methoxyethyl nucleotides flanking a region of 2'-deoxynucleotides" and claim 60 adds "wherein each region of 2'-methoxyethyl nucleotides consists of 5 nucleotides and the region of 2'-deoxynucleotides consists of 10 nucleotides". Applicant asserts that support for the limitation in the new claims filed 9/20/05 [claims 54-68] can found throughout the specification and claims as originally filed. Upon a review of the specification and claims as originally filed such support was not readily apparent and the limitation above are

considered new matter. If applicant believes that the specification and/or claims as originally filed provide support for the limitation above applicant should point to such support with particularity.

Allowable Subject Matter

Claims 70-72 are allowed.

Claims 68 and 69 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-7, 13-16, 23, 49-51, 59, and 60 are rejected under 35 U.S.C. 102(e) as being anticipated by Watt [US 6,468,796]

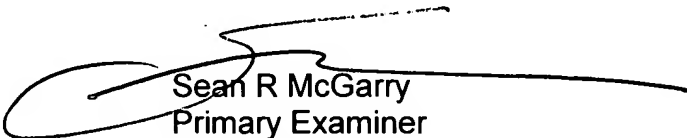
The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Watt et al disclose and antisense oligonucleotide (SEQ ID NO: 85) that comprises at least an 8 nucleobase portion of SEQ ID NO: 122 and is 20 nucleotides in length. Watt discloses the "RNA" limitation of claim 6 at column 6. The limitations of claims 7, 49-51, 59, and 60, drawn to "chimeric and gapmers", are disclosed at column 11 and also LNA at column 8 (see also references incorporated by reference). The limitations of claims 13-15 are disclosed in columns 6-12. At column 9 it is disclosed the limitations of claim 9. At column 14 it is disclosed the limitations of claim 23. Applicant is also directed to claims 1-25 of Watt which also discloses SEQ ID NO: 85, 5-methylcytosine modifications, chimeric oligonucleotides, modification to the sugar, nucleobasebase or internucleoside linkage, and 2'-O-methoxyethyl modifications, for example.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R. McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Sean R McGarry
Primary Examiner
Art Unit 1635